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(54) Title: INTERFACE TO FES CONTROL SYSTEM

(57) Abstract: A functional electrical stimulation system (30) for controlling the movement of a portion of a body of a subject (12), such as the subject's legs. The system (30) comprises a sensor (60) that in one arrangement is mountable to a portion of the subjects' body other than the legs, for example the torso (14). In another arrangement, the sensor (60) can be mountable to a walking aid, such as a crutch (20). The sensor (60) outputs signals representative of the position and/or movement of the torso (14) or walking aid (20). The system (30) also comprises a control means (32) that receives and processes the signals output by the sensor (60) and outputs control signals to a stimulator (35) adapted to provide electrical stimulation to the legs via electrodes (53) in response to the position and/or movement of the torso (14) or walking aid (20) as determined by the sensor (60).

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## Interface to FES control system

### Field of the Invention

The present invention relates to a functional electrical stimulation  
5 (FES) system and method of using such a system. More particularly, the  
invention relates to a device and method for providing a person using  
functional electrical stimulation with a means of controlling the electrical  
stimulation provided to their limbs.

### Background of the Invention

10 In the area of medical technology, much advancement have been made  
to assist individuals who have previously been considered to be disabled in  
some way, to lead a relatively normal life in spite of such disabilities. Such  
advancements include the provision of hearing aids and cochlear implants  
for the hearing impaired, as well as pacemakers for those who experience  
15 cardiac problems, to name a few. However with regard to persons suffering  
from spinal cord injury and those who have lost function of their limbs, the  
provision of a device or devices to return desired function to the individual  
has as yet proven difficult to implement. Functional electrical stimulation  
(FES) systems of various types are seen to have particular application in  
20 providing persons suffering from spinal cord injury or deficiency, such as  
paraplegia, with a capacity to make controlled movements of their  
dysfunctional legs.

Functional electrical stimulation systems use electronics to generate  
electrical impulses. These impulses are then delivered to the nerves or  
25 muscles of a subject via electrodes to stimulate movement of the muscles  
that are otherwise dysfunctional. In order for useful and controlled  
movements of limbs to be achieved several muscles must usually be operated  
in concert. This is normally achieved by an algorithm executed under the  
control of the FES system to deliver a pattern or sequence of stimulation  
30 impulses.

An important aspect of the successful implementation of such an FES  
system is the provision of a control technique that controls the limbs of a  
patient so that they follow a desired trajectory. It is extremely difficult,  
however, to choose a trajectory of the limbs so that a functional task such as  
35 standing is performed. In one proposal, control is provided by a touch pad

interface which can be activated by the subject's fingers to some control types of movement, such as standing, sitting and walking.

Such touch pad interfaces as known in the art do not provide an intuitive interface for the subject with the FES system and assume that the subject has full hand control to enable use of such a device. Existing FES systems are, therefore, relatively difficult to learn how to use and require a certain amount of dexterity which has the potential to move subjects in undesirable ways.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention before the priority date of each claim of this application.

#### Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is a functional electrical stimulation system for controlling the movement of a portion of a body of a subject comprising:

a measuring means having at least one sensor, mountable to a portion of the subject's body other said body portion, that outputs signals representative of the position and/or movement of said other portion of the subject's body; and

a control means that receives and processes the signals output by the measuring means and outputs control signals to a stimulating means adapted to provide electrical stimulation to said body portion in response to the position and/or movement of said other body portion determined by the measuring means.

In one embodiment of this aspect, the said other body portion is selected from the group comprising the torso, the head or one or both arms of the subject.

In a further embodiment, said body portion is one or both legs of the subject.

The present invention provides a system that can be relatively easily used, in one arrangement, to generate one or more desired angles between  
5 the respective thighs and lower legs of a paraplegic with the legs being controlled by electrical stimulation of the muscles so that the actual measured angle of the thigh and lower leg corresponds to the desired angles.

In a preferred embodiment, the measuring means measures the angle of the subject's torso relative to a predetermined plane. The predetermined  
10 plane can be a sagittal plane, a frontal plane or a horizontal plane. In one embodiment, the measuring means only measures the angle when the torso has stopped gross movement. In another embodiment, the measuring means measures the angle throughout the range of movement of the torso.

In another embodiment, the measuring means detects torso movements  
15 that are determined by the control means as indicative that the subject wishes to roll over when they are in a horizontal position, such as when they are asleep. Such torso movements will typically comprise twisting movements of the torso.

In yet another embodiment, the measuring means measures the angle  
20 of the torso relative to the position of one or both of the lower limbs of the subject.

In one embodiment, the measuring means can be carried by the subject. The measuring means may be carried in a harness or clothing worn by the subject. In another embodiment, the measuring means may be  
25 strapped about the torso of the subject. In an alternative embodiment, the measuring means or componentry thereof can be implantable within the subject.

In a preferred embodiment, the measuring means comprises one or more transducers that outputs signals representative of the position and/or  
30 movement of the transducer to the control means. Where the measuring means is measuring the angle of the torso relative to the lower limbs, a transducer can be mounted on the torso and on one or both of the lower limbs. More than one transducer mounted on the torso and/or the lower limbs can be envisaged. Each of the transducers in this case would output  
35 signals to the control means.

The control means preferably processes the output signals of the transducer or transducers and then outputs signals to the stimulating means to provide electrical stimulation to the muscles of the subject. The control means can execute an algorithm that leads to provision of electrical  
5 stimulation to the appropriate muscle(s) at the appropriate intensity as dictated by the subject or a predetermined programme. The output signals of the transducer or transducers and those of the control means to the stimulating means can comprise electrical or optical signals.

In a further embodiment, the control means can have a storage means  
10 having at least one predetermined action sequence storable therein. On receipt of signals from the measuring means, said at least one predetermined action sequence can be provided to the stimulating means. The predetermined action sequence can result in the subject moving from a standing to a sitting position, or moving from a sitting to a standing position,  
15 walking, or moving the legs in a pedalling action. Other suitable predetermined action sequences can be envisaged.

In one embodiment, the control means is adapted to output a pre-determined sequence of signals to the stimulating means upon receiving signals from the transducer or transducers that the subject's torso is at a  
20 particular pre-determined angle relative to a plane, such as a notional horizontal plane, or the lower limbs. For example, when the subject bends their torso forward from the hip this can be measured by the transducer with appropriate signals provided to the control means.

In one embodiment, the pre-determined sequence of signals to the  
25 stimulating means can be output by the control means when the torso has bent forward by an angle of between about 10° and about 60°, more preferably between about 25° and 50°, and still more preferably between about 25° and 45°.

In another embodiment, the control means is adapted to output a series  
30 of pre-determined signals representative of the position of the subject's torso. A particular series of various positions of the torso can cause the control means to output a particular series of signals to the stimulating means so causing a particular series of stimulations to the muscles of the subject. This allows a subject to learn a particular series of movements that lead to a  
35 particular desired series of movements of the stimulated limbs of the subject. For example, a movement or series of movements of the torso may initiate a

step by a leg or a series of steps by the subject's legs. Alternatively, a movement or a series of movements of the torso may initiate a standing or sitting action.

In response to the detection of signals from the control means, the stimulating means is adapted to output electrical impulses. These impulses are transmitted to the subject's nerves or muscles from a stimulator through electrically conducting leads to stimulation electrodes. The electrodes can be surface mounted on the skin of the subject, percutaneous intramuscular electrodes that are implanted with a minimally invasive needle insertion procedure, or fully implanted electrodes. The stimulating means preferably has circuitry adapted to drive whatever electrodes are selected for use with a particular subject.

In one embodiment, the stimulator can be carried by the subject. The stimulator can be carried in a harness or clothing worn by the subject. In another embodiment, the stimulator may be strapped to the subject. In an alternative embodiment, the stimulator or componentry thereof can be implanted within the subject. The electrical leads extending from the stimulator to the electrodes can be totally implantable within the subject or carried externally on the body of the subject.

In a preferred embodiment, the electrodes can be mounted to the lower limbs of the subject. It will be envisaged that the electrodes could be mounted to the upper limbs or that electrodes may be mounted to both the upper and lower limbs of the subject.

Where the electrodes are mounted to the lower limbs, the pre-determined sequence of signals generated by the control means is provided to the lower limbs.

In the embodiment where a bend of the torso to a pre-determined angle relative to the horizontal plane is made, the control means can be programmed such that the pre-determined sequence of signals generated on detection of such a change in the position of the torso causes the subject to be moved from a sitting position to a standing position or vice versa.

As discussed above, in another embodiment, a particular series of various positions of the torso can cause the control means to output a particular series of signals to the stimulating means so causing a particular series of stimulations to the muscles of the subject. For example, when the subject is in a particular pre-determined position, the angle of the torso

relative to the horizontal plane can determine the angle between the thigh and lower leg of each leg of the subject. The control means preferably only allows torso movement to control limb angle when the subject is in a position that variation in limb angle is appropriate or safe for the subject. When the torso is upright, the angle between the torso and the horizontal plane is about 90°. If the angle between the thigh and lower leg is not about 90°, the stimulating means stimulates the muscles within the leg until this angle is achieved. This should be relatively comfortable for the subject as when sitting upright in a chair a person's thighs are typically about normal to the lower leg. When the subject bends their torso relatively forward, the angle between the torso and the horizontal plane decreases. This decrease in angle leads the control means to output signals causing flexion of the lower leg, preferably to a predetermined degree, so moving the feet to a position ready to allow the subject to stand. Once the feet are in position, the subject can, for example, move their torso backwardly relative to the horizontal plane. This movement, if detected by the control means following the previous forward movement, can lead the control means to cause full extension of the legs so moving the subject from a sitting to standing position.

Detection of other movements of the torso can lead the control means to output other pre-programmed sequences of signals. For example, if the subject considers that they are not in a position to stand once the feet have been moved the predetermined degree, a further forward or other movement of the torso can cause the control means to stimulate the lower leg to return to a position about 90° relative to the thigh so leaving the subject in a sitting position.

When a subject is in a standing position, controlled movement of the torso can allow the subject to move to a sitting position. For example, forward bending of the torso relative to the horizontal plane (so decreasing the angle of the torso to the notional horizontal plane) can cause the control means to stimulate the legs of the subject to decrease the angle between the thigh and lower leg from about 180° gradually towards about 90° at which point the legs are in a position to allow the subject to comfortably sit upon a chair.

In another embodiment, when the subject is in a particular predetermined position, variation in the angle of the torso and/or head, or both in combination, relative to the lower limbs can allow a subject to control

initiation of a step or sequence of steps. Sequential variations in torso position relative to the lower limbs can control a series of alternate steps by the subject's legs. Preferably, the subject can learn to perform this sequential variation in torso and/or head angle and so control their step movement.

- 5 Again, the control means preferably only allows torso movement to control step initiation when the subject is in a position that step initiation is appropriate or safe for the subject.

A system of using torso and/or head angle allows the subject to define their preferred limb angle. This allows the subject to be trained to control  
10 the standing and sitting process or walking using the FES system. This gives the subject a greater sense of controlling the stimulation provided to their limbs rather than being in a position of feeling that the system is entirely in control of their movement. This is envisaged as providing the subject with a greater sense of confidence in using function electrical stimulation systems  
15 so leading to greater use of the system.

As discussed above, the control means can be adapted to output a predetermined sequence of signals to the stimulating means on receiving signals from the transducer that the subject is twisting their torso in a manner indicative that the subject wishes to roll over. In this case, the stimulating  
20 means can be adapted to stimulate the legs in a manner that assists the subject in turning over. In one embodiment, the system will assist turning over when the subject is asleep. In this case, it is preferred that the stimulations to the legs are just sufficient to assist turnover without being of a magnitude that significantly disturbs the sleep of the subject.

25 In a preferred embodiment, stimulation of the legs to assist turning over is only activated by the control means when the patient is lying in a substantially horizontal plane. For example, the transducer can determine the orientation of the subject and provide a signal to the control means representative of the orientation. In such instances, whenever the transducer  
30 is outputting a signal that indicates that the subject is not substantially horizontal, the control means is locked from outputting the signal sequence that would be employed to assist rolling over.

In another embodiment, the control means can be programmed to output signals to the stimulating means to cause roll over of the subject at  
35 predetermined times or at predetermined rates. For example, the control means can be programmed to output signals causing roll over of the subject



at least 2 times in an 8 hour period. These roll overs could be additional to those that occur in response to detection of torso twisting or movement indicating a desire by the subject to roll over. In one embodiment, the control means could monitor the number of assisted roll overs performed in response to torso movement or twisting and only institute an involuntary roll over if the subject has not rolled over for a predetermined minimum period of time. For example, the control means may be adapted to institute an involuntary roll over if no roll over has occurred for at least 4 hours.

Assistance in rolling over provided by the present system should reduce the incidence of pressure sores and disrupted sleep for spinal cord injured persons who are unable to relieve pressure during sleep by rolling over.

In a preferred embodiment, the system includes a feedback means that measures the position and/or movement of said body portion being stimulated by the stimulating means and provides output signals to the control means representative of these measurements. The feedback means can comprise one or more transducers mounted to the limbs being stimulated. Where a subject's legs are being stimulated, one or more transducers may be mounted to the thigh and/or lower leg of the subject. In another embodiment, the transducers can be fully implantable within the legs.

The signals provided by the feedback means can be used to override the instruction provided by the subject by bending their said other body portion, such as their torso, if the control means detects that the limbs are in an unsuitable position to be stimulated. Once stimulation has commenced, for example to cause the subject to stand, the control means can also use the output signals of the feedback means to determine if the limbs of the subject are responding and to adjust the pattern and location of the stimulation if required. Such a feedback means provides the system with the flexibility to adjust its performance depending on the circumstances faced by the subject. For example, a different stimulation pattern may be required to successfully move a subject from a sitting position on a low couch to a standing position compared to that required to achieve the same result from sitting in an upright chair.

The signals provided by the feedback means can also be used by the control means as a means of determining if the subject is in a substantially

horizontal position. If the feedback means outputs signals to the control means that the subject is not substantially horizontal, the control means is preferably locked from outputting the sequence of signals that would normally be output to the stimulating means to assist rolling over on  
5 detection of torso movements normally indicative that the subject does wish to roll over.

In a preferred embodiment, the control means has an operating means. The operating means preferably comprises an activation and deactivation means. The activation and deactivation means preferably allows the subject  
10 to turn on and off the control means and the FES system when desired. Where the FES system is fully implanted, the activation and deactivation means is preferably controllable from outside the body. In one embodiment, the activation and deactivation means can comprise a switch. Where the control means is implanted, the system preferably can still be operated  
15 through the skin of the subject. The operating means preferably incorporates a locking means to prevent inadvertent activation or deactivation.

Where implanted, an external controller can communicate with the implanted unit using radio frequency (RF) transmissions.

According to a further aspect, the present invention is a functional  
20 electrical stimulation system for controlling the movement of a portion of a body of a subject comprising:

a measuring means having at least one sensor, mountable to a walking aid, that outputs signals representative of the position and/or movement of said walking aid when operated by a subject of the system; and

25 a control means that receives and processes the signals output by the measuring means and outputs control signals to a stimulating means adapted to provide electrical stimulation to said body portion in response to the position and/or movement of said walking aid determined by the measuring means.

30 In this aspect, the subject can learn a series of positions and/or movements of the aid that cause pre-programmed control signals or sequences thereof to be supplied to the stimulating means.

In one embodiment, the walking aid can comprise a crutch or walking stick. Placement of the crutch or stick at a particular angle relative to  
35 vertical or its movement in a particular way can be pre-programmed to cause stimulation of a lower limb in a manner that allows the subject to walk. In a

preferred embodiment, the system relies on at least one measuring means mounted on respective crutches supporting the subject. A particular movement or position of the left crutch can be adapted to cause stimulation of the right leg. A subsequent particular movement or position of the right crutch can be adapted to cause stimulation of the left leg. In this manner, a subject can learn to walk using the FES system by alternately moving or adjusting the position of the crutches used to support them. In an alternative arrangement, it can be envisaged that the subject rely on one crutch or walking stick. In this case, variation in the position and/or movement of the aid can lead to stimulation of the opposing leg. The adjacent leg can then be stimulated to take a stride 180° out of phase of the opposing leg.

In this aspect, the monitoring means, control means and stimulating means can have the features of the equivalent systems already defined herein.

According to a still further aspect, the present invention is a walking aid for a subject being assisted to walk using functional electrical stimulation system, the walking aid having at least one sensor mounted thereon that outputs signals representative of the position and/or movement of the walking aid.

In this aspect, the functional electrical stimulation system can have the features of the FES system defined above.

In this aspect, the walking aid can comprise a crutch. The crutch can comprise a tall crutch that fits under the armpits with double uprights and a small horizontal hand bar extending between the uprights, a Lofstrand crutch which consists of a single tube of aluminium surrounded by a metal cuff that fits around the forearm and has a handbar positioned proximally thereto, or a Canadian elbow extensor crutch which is a variation of the Lofstrand crutch. Still further, the walking aid can comprise a walking stick.

The walking aid can have an on-board power supply, such as a rechargeable battery, that provides power to the sensor. In another embodiment, componentry of the FES system, such as the control means and stimulator can be mounted on or in the walking aid. Electrical connectors can also be incorporated into the walking aid to allow cables to extend from the componentry mounted to or in the walking aid to the one or more transducers and/or the stimulating electrodes.

According to a further aspect, the invention is a method of controlling functional electrical stimulation provided to a portion of a body of a subject, the method comprising the steps of:

- measuring the position and/or movement of a portion of the body of
- 5 the subject other than said body portion; and
- processing the signals and outputting electrically stimulation to said body portion in response to the measured position and/or movement of said other body portion.

In a preferred embodiment of this aspect, the method is adapted to use

10 the position and/or movement of the torso, the head, one or both arms, or a combination thereof, to control the stimulation provided to the legs of the subject. In a particularly preferred embodiment, the position and/or movement of the torso and/or head can be used to initiate and control a standing or sitting action of the subject. In another embodiment, the

15 movement of the torso and/or head can be used to initiate stimulation of the legs that allows the subject to roll over when in a substantially horizontal position.

According to a still further aspect, the invention is a method of controlling functional electrical stimulation provided to a portion of a body

20 of a subject, the method comprising the steps of

- measuring the position and/or movement of a walking aid operated by the subject; and
- processing the signals and outputting electrical stimulation to said body portion in response to the measured position and/or movement of said
- 25 walking aid.

In a preferred embodiment of this aspect, the electrical stimulation is provided to the legs of the subject to cause the subject to walk.

In a preferred embodiment of these latter aspects, the method includes a step of measuring the position and/or movement of the legs and using the

30 measurements to modify or control the electrical stimulation generated in response to movement of the subject's torso or walking aid.

#### Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawing, in which:

Fig. 1 is a sequence of drawings depicting the movement of a subject's body from a sitting position to a standing position using functional electrical stimulation;

Fig. 2 is a sequence of drawings depicting the movement of a subject's body from as standing position to a sitting position using functional electrical stimulation;

Fig. 3 is a side elevation view of one embodiment of a walking aid according to the present invention;

Fig. 4 is a sequence of drawings depicting the gait of a person using walking aids in concert with a functional electrical stimulation system; and

Fig. 5 is a simplified block diagram depicting one embodiment of a FES system according to the present invention.

#### Preferred Mode of Carrying out the Invention

A FES system according to the present invention is generally depicted as 30 in Fig. 5.

The system has a housing 31 that houses a control means 32 and a stimulator 35. A power source in the form of a rechargeable battery 43 is also provided in the housing 31. The depicted control means 32 receives a first set of signals through a first signal path 33 provided by a cable 40 extending from a first transducer 60 to an electrical connector 33a on the housing 31. The transducer 60 and cable 40 are depicted schematically in Fig. 5 and are not shown to scale. The transducer 60 is adapted to be mounted to a portion of the body of the subject that is under the control of the subject. For example, in the case of subject with paraplegia, the transducer can be mounted to the upper torso of the subject.

The signals output by transducer 60 and provided through signal path 33 represent the magnitude and type of movement of the torso made by the subject.

While the control means 32 could rely only on the input from transducer 60, the depicted control means 32 also receives a second set of output signals through a second signal path 34 provided by a cable 50 extending from a transducer 61. Transducer 61 can also be mounted to the torso of the subject or at another location on the subject's body. While depicted schematically in Fig. 5, the cables 40,50 can be envisaged as being a flexible cables extending between the respective transducers 60,61 and the connectors 33a,34a of the housing 31. The signals output by transducer 61

and provided through signal path 34 can also represent the magnitude and type of movement made by the portion of the subject's body to which the transducer 61 is mounted.

In one arrangement, the control means 32 receives the first set of  
5 output signals through the first signal path 13 from transducer 60 when mounted to the torso of the subject and the second set of output signals through the second signal path 34 from transducer 61 mounted to one of the legs of the subject. While Fig. 5 depicts only one transducer providing signals through each of the signal paths 33 and 34, more than one transducer  
10 could be utilised to provide signals through each signal path.

The transducer 60 mounted to the torso of the subject 12 provides a signal output representative of the angle of the torso relative to a horizontal plane and the movement of the torso. The transducer 61 mounted to one of the legs of the subject provides a signal output representative of the angle of  
15 the thigh of the leg relative to a horizontal plane and the movement of the legs. When monitoring only one leg, the control means 32 can be operated in a manner that assumes the other leg is in a position 180° out of phase to the monitored leg, when the subject is receiving functional electrical stimulation that results in the subject being able to walk or move their legs in some  
20 repetitive manner, such as rotate the pedals of an exercise bicycle.

Fig. 1 depicts one use of one embodiment of the FES system 30 depicted in Fig. 5. In Fig. 1, a simplified view of a subject 12 receiving functional electrical stimulation is depicted. In Fig. 1a, the subject 12 is shown seated on a chair 13. As shown in Fig. 1b, the subject 12 can move  
25 their torso 14 forwardly to a position that is at a particular angle relative to a horizontal plane. The transducer 60 mounted to the torso 14 detects this movement and outputs signals representative of this to the control means 32. The control means 32 on receipt of these signals in turn outputs suitable control signals to the stimulator 35 which outputs electrical impulses to  
30 electrodes 53 mounted to the legs 15 of the subject 12. For reasons of clarity, the system 30 and electrodes 53 are not depicted in Fig. 1

As can be seen in Fig. 1b, as the subject 12 moves their torso 14 forward, the lower legs of the subject 12 move backwardly. The angle of the torso 14 controls the angle of movement of the lower legs about the knees of  
35 the subject 12.

Once the feet of the subject 12 are in the correct position, the subject 12 can return their torso 14 back to an upright position as depicted in Fig. 1c. This movement leads to further signals being output to the control means 32. Once the torso 14 is back in an upright position, the control means 32 can  
5 output control signals to the stimulator 15 which result in the stimulator 35 outputting a sequence of stimulation impulses to the legs 15 that result in the subject 12 moving to a standing position (see Figs. 1d and 1e).

Fig. 2 depicts another use of an embodiment of the FES system 30. In these figures, the subject 12 is firstly shown standing in front of a chair 13.  
10 On a subject 12 moving their torso 14 forward a particular desired angle, such as greater than 30°, and then returning to an upright position within a predetermined time (see Fig. 2a), the transducer 60 detects this combination of movements and outputs appropriate representative signals to the control means 32. The control means 32 on receiving this combination of signals,  
15 outputs control signals to the stimulator 35 which results in the thighs of the subject 12 bending backwardly relative to the knees (see Fig. 2b) so as to move the subject 12 back down onto the chair 13 as depicted in Fig. 2c.

Figs. 1 and 2 depict examples of how the FES system 30 can be used by the subject 12 adjusting their torso to control the movement of their  
20 dysfunctional legs.

The control means 32 is programmed to output a particular stimulation signal sequence to the stimulator 35 on detection of a predetermined torso position adopted by the subject 12. In this way, the subject 12 can learn to create particular different stimulation patterns or signal sequences by the  
25 stimulator 35 by adopting various different torso positions.

While the use of torso orientation is depicted in Figs. 1 and 2 for initiating a standing up or sitting down action, torso orientation changes can also be used to initiate and maintain a walking sequence. In another embodiment, the control means 32 can be adapted to watch for twisting  
30 movements of the torso that are indicative, when the subject is laying down, that the subject wishes to roll over. The control means can also include a timer means that ensures the subject 12 rolls over a predetermined number of times in a particular time period.

The transducer 61 mounted to the legs of the subject 12 can also be  
35 utilised as a means of feeding back information to the control means 32 following electrical stimulation of the legs by the stimulator 35. For

example, the transducer 61 can inform the control means 32 that the stimulator 35 has or has not achieved the outcome for the legs expected by the provided stimulation.

5 The control means 32 can also control the stimulation applied by the stimulator 35 based on a comparison of angles or orientation of the torso relative to the upper and lower leg (knee) angle. As previously mentioned, the detected torso angle relative to the horizontal plane can be approximated to the desired knee angle such that the desired knee angle can be considered as a function of the measured torso angle. The control means 32 can then  
10 initiate appropriate signals to ensure that the actual knee angle closely approximates that of the desired knee angle based on a model of desired knee angles and torso angles.

The depicted control means 32 comprises a microprocessor and includes a data storage buffer that stores measured torso movements  
15 measured by the transducer 60 and/or leg movements resulting from the provision of electrical stimulation thereto.

One embodiment of a crutch for use as a walking aid according to the present invention is depicted generally as 20 in Fig. 3. The depicted crutch  
20 comprises a standard tall crutch, however, the present invention could also equally rely on a Lofstrand crutch or Canadian elbow extensor crutch.

The crutch 20 has an armpit portion 21 and two double uprights 22 that extend from the armpit portion 21 to a foot 23. A small horizontal handbar 24 extends between the uprights 22 which allows the subject 12 to use and support themselves on the crutch 20.

25 Mounted to the crutch 20 below the handbar 24 is a transducer 25. The transducer 25 can have the same or different features to that of transducer 60 described above. Extending from the transducer is a cable 26. In the depicted embodiment, cable 26 is adapted to be electrically connected to connector 33a of the FES system 30. The transducer 25 is used to provide  
30 signals to the control means 32 in replacement of or in addition to signals provided by transducer 60 mounted to the torso of the subject 12. By varying the position of one or two crutches being used by the subject 12, the subject 12 can control the stimulation pattern output by the stimulator 35. In one example, forward movement of the left crutch can result in a forward step of  
35 the right leg of the subject 12 and subsequent forward movement of the right crutch can result in a forward step of the left leg of the subject 12. Further



the control means 32 of this embodiment can determine the distance between the subject's leg and the associated crutch and cause the leg to be brought towards the crutch when the distance exceeds a specific limit. By learning to appropriately move the supporting crutches, a subject 12 can  
5 create a sequence of steps using the FES system 30.

While Fig. 3 only depicts the transducer 25 mounted to the crutch 20, in another embodiment, the housing 31 could be mounted on the crutch 20.

Fig. 4 depicts a subject 12 using a walking stick in each hand to control the FES system 30 in a manner similar to that described for crutch 20.

10 Walking stick 27a is in the right hand of the subject 12 and walking stick 27b in the left hand. For the purposes of clarity, the left leg, left arm and left walking stick 27b of the subject 12 are depicted in phantom in Fig. 4.

Each walking stick 27a,27b has a transducer 25 mounted thereon (not visible) that is used to provide signals to the control means 32 in replacement  
15 of or in addition to signals provided by transducer 60 mounted to the torso of the subject 12. By varying the position of the sticks 27a,27b, the subject 12 can control the stimulation pattern output by the stimulator 35.

In one example, forward movement of the left stick 27b can result in a forward step of the right leg 15a of the subject 12 and subsequent forward  
20 movement of the right stick 27a can result in a forward step of the left leg 15b of the subject 12. As depicted in Fig. 4b, the subject 12 has moved the left stick 27b forward which in turn has resulted in the subject's right leg 15a stepping forward a distance similar to or the same as that moved by the left stick 27b. Once this step is complete, the subject 12 can move the right stick  
25 27a forward (as depicted in Fig. 4c) which in turn leads the FES system 30 to move the left leg 15b forward a distance similar to or the same as that moved by the right stick 27a. By continuously moving the sticks 27a,27b forward in alternate fashion, the subject 12 can walk across a surface.

While the use of the sticks 27a,27b is depicted in Fig. 4 as resulting in  
30 a walking movement of the subject 12, it will be appreciated that other movements of one or both sticks can result in other movements of the subject 12. For example, the lifting of one of the sticks may cause the subject to sit or stand.

The components of the depicted FES system 30 can be fully implanted  
35 within the subject 12. It will, however, be appreciated that the control means 32 and other components could be external the body of the subject 12.

Electrical stimulation to the muscles is provided, in the depicted embodiment, by electrodes 53 mounted to the skin or implanted within the muscles identified as requiring stimulation to achieve the movement desired when installing the system 30. As depicted in Fig. 5, the electrodes 53 are  
5 electrically connected by cables 54 to the output of stimulator 35 through a connector 35a on the housing 31.

As depicted in Fig. 5, the system 30 further comprises an operating means 36 that receives signals from a transducer 37 adapted to monitor the position of another portion of the subject's body, such as the subject's head.  
10 The transducer 37 outputs signals through cable 38 connected to connector 39 in the housing 31. The transducer 37 and cable 38 are not depicted to scale. More than one such transducer 37 can also be envisaged. On receipt of a predetermined signal from the transducer 37, the operating means can activate or deactivate the control means 32 and/or the stimulator 35. For  
15 example, the transducer 37 can be mounted to the head of the person 12, and adapted to output a predetermined signal on determination of a particular movement of the person's head relative to their torso. This provides the person 12 with a ready means to activate or deactivate the FES system 30 simply by a predetermined movement of their head. It can be envisaged that  
20 movement of the subject's torso 14 or the walking aid 20 held by the person 12 could also be used to activate or deactivate the control means 32 and/or the FES system 30.

The FES system 30 provides a relatively easier and more natural interface for the subject 12 to initiate a step or other movement when  
25 compared to button presses using known touch pad interfaces.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to  
30 be considered in all respects as illustrative and not restrictive.

**CLAIMS**

1. A functional electrical stimulation system for controlling the movement of a portion of a body of a subject comprising:
  - 5 a measuring means having at least one sensor, mountable to a portion of the subject's body other said body portion, that outputs signals representative of the position and/or movement of said other portion of the subject's body; and
  - a control means that receives and processes the signals output by the measuring means and outputs control signals to a stimulating means adapted to provide electrical stimulation to said body portion in response to the position and/or movement of said other body portion determined by the measuring means.
- 15 2. A functional electrical stimulation system of claim 1 wherein said other body portion is selected from the group comprising the torso, the head, one or both arms, and a combination thereof.
3. A functional electrical stimulation system of claim 2 wherein said  
20 body portion is one or both legs of the subject.
4. A functional electrical stimulation system of claim 2 wherein the measuring means measures the angle of the subject's torso relative to a predetermined plane selected from the group comprising a sagittal plane, a  
25 frontal plane or a horizontal plane.
5. A functional electrical stimulation system of claim 4 wherein the measuring means only measures the angle of the torso when the torso has stopped gross movement.  
30
6. A functional electrical stimulation system of claim 4 wherein on detecting twisting movements of the torso and that the subject is at least substantially horizontal, the control means outputs control signals that cause the stimulating means to output a sequence of stimulation impulses that  
35 serve to roll the subject over.

7. A functional electrical stimulation system of claim 1 wherein the measuring means comprises at least one transducer.
8. A functional electrical stimulation system of claim 7 wherein said at  
5 least one transducer is implantable within the subject.
9. A functional electrical stimulation system of claim 1 wherein the control means further comprises a storage means having at least one predetermined action sequence storable therein, and further wherein, on  
10 receipt of signals from the measuring means, said at least one predetermined action sequence is provided to the stimulating means.
10. A functional electrical stimulation system of claim 9 wherein said at least one predetermined action sequence results in the subject moving from a  
15 standing to a sitting position, or moving from a sitting to a standing position, walking, or moving the legs in a pedalling action.
11. A functional electrical stimulation system of claim 4 wherein the control means outputs control signals to the stimulating means when the  
20 torso of the subject is bent forward by an angle of between about 10° and about 60°, more preferably between about 25° and about 50°, and still more preferably between about 25° and about 45° relative to a notional horizontal plane.
12. A functional electrical stimulation system of claim 1 wherein the  
25 stimulating means comprises a stimulator and at least one electrode mountable on said body portion and electrically connected to the output of the stimulator.
13. A functional electrical stimulation system wherein the system further  
30 comprises an override means that monitors the position of said subject and prevents provision of electrical stimulation to said body portion if the position of said subject is such that stimulation is inappropriate or unsafe for the subject.

14. A functional electrical stimulation system of claim 6 wherein the control means is programmed to output signals to the stimulating means to cause roll over of the subject at predetermined times.
- 5 15. A functional electrical stimulation system of claim 14 wherein the control means is programmed to output signals causing roll over of the subject at least 2 times in an 8 hour period.
- 10 16. A functional electrical stimulation system of claim 1 wherein the system further comprises a feedback means that measures the position and/or movement of said body portion being stimulated by the stimulating means and provides output signals to the control means representative of these measurements.
- 15 17. A functional electrical stimulation system of claim 1 wherein the control means has an operating means having an activation and deactivation means that allows the subject to turn on and off the control means and/or the FES system when desired.
- 20 18. A functional electrical stimulation system for controlling the movement of a portion of a body of a subject comprising:  
a measuring means having at least one sensor, mountable to a walking aid, that outputs signals representative of the position and/or movement of said walking aid when operated by a subject of the system; and  
25 a control means that receives and processes the signals output by the measuring means and outputs control signals to a stimulating means adapted to provide electrical stimulation to said body portion in response to the position and/or movement of said walking aid determined by the measuring means.
- 30 19. A functional electrical stimulation system of claim 18 wherein the walking aid comprises a crutch or walking stick.
- 35 20. A functional electrical stimulation system of claim 19 wherein variation in movement and/or position of the crutch or stick causes

stimulation of the legs of the subject in a manner that allows the subject to walk.

21. A functional electrical stimulation system of claim 20 wherein at least one measuring means is mounted on respective crutches supporting the subject.

22. A walking aid for use by a subject being assisted to walk using functional electrical stimulation system, the walking aid having at least one sensor mounted thereon that outputs signals representative of the position and/or movement of the walking aid.

23. A walking aid of claim 22 wherein the functional electrical stimulation system is as defined in claim 18.

24. A walking aid of claim 22 wherein the walking aid comprises a crutch.

25. A walking aid of claim 24 wherein the crutch is selected from the group comprising a tall crutch, a Lofstrand crutch, and a Canadian elbow extensor crutch.

26. A walking aid of claim 22 wherein the walking aid is a walking stick.

27. A walking aid of claim 22 wherein the walking aid has an on-board power supply that provides power for at least the sensor.

28. A method of controlling functional electrical stimulation provided to a portion of a body of a subject, the method comprising the steps of:  
measuring the position and/or movement of a portion of the body of the subject other than said body portion; and  
processing the signals and outputting electrically stimulation to said body portion in response to the measured position and/or movement of said other body portion.

29. A method of controlling functional electrical stimulation provided to a portion of a body of a subject of claim 28 wherein said other body portion is

selected from the group comprising the torso, the head, one or both arms, and a combination thereof.

5 30. A method of controlling functional electrical stimulation provided to a portion of a body of a subject of claim 29 wherein said body portion is the legs of the subject.

10 31. A method of controlling functional electrical stimulation provided to a portion of a body of a subject of claim 30 further comprising the step of measuring the position and/or movement of the legs and using the measurements to modify or control the electrical stimulation generated in response to movement of the subject's other body portion.

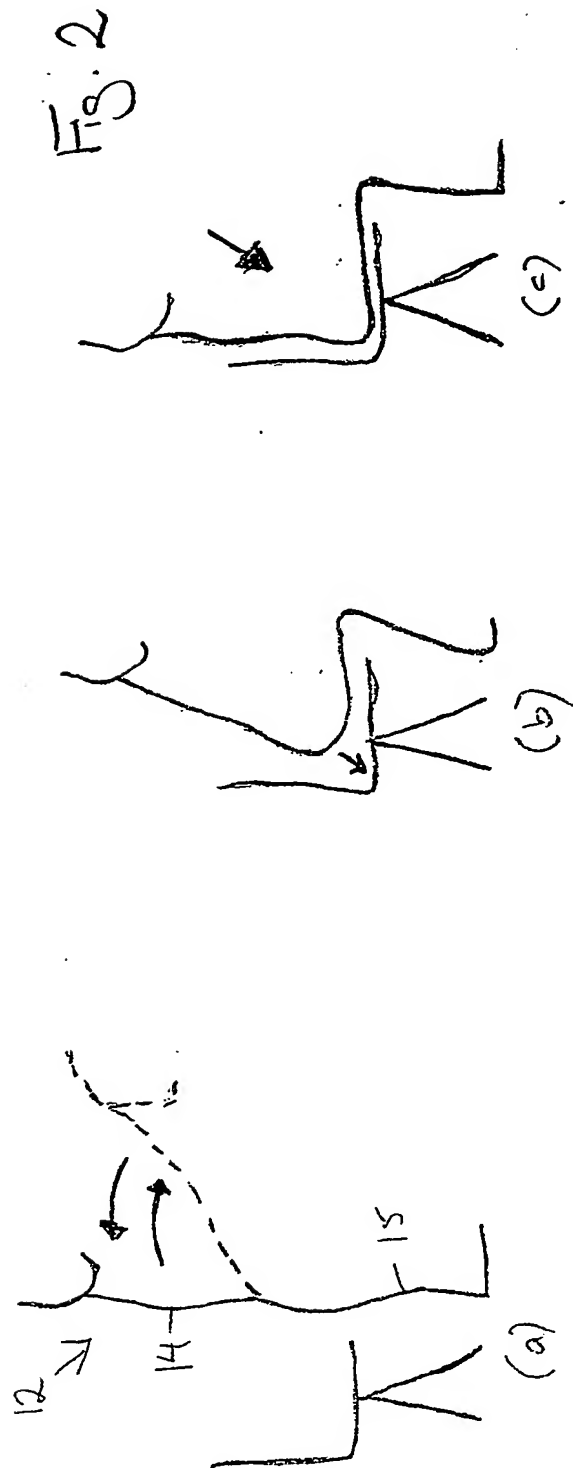
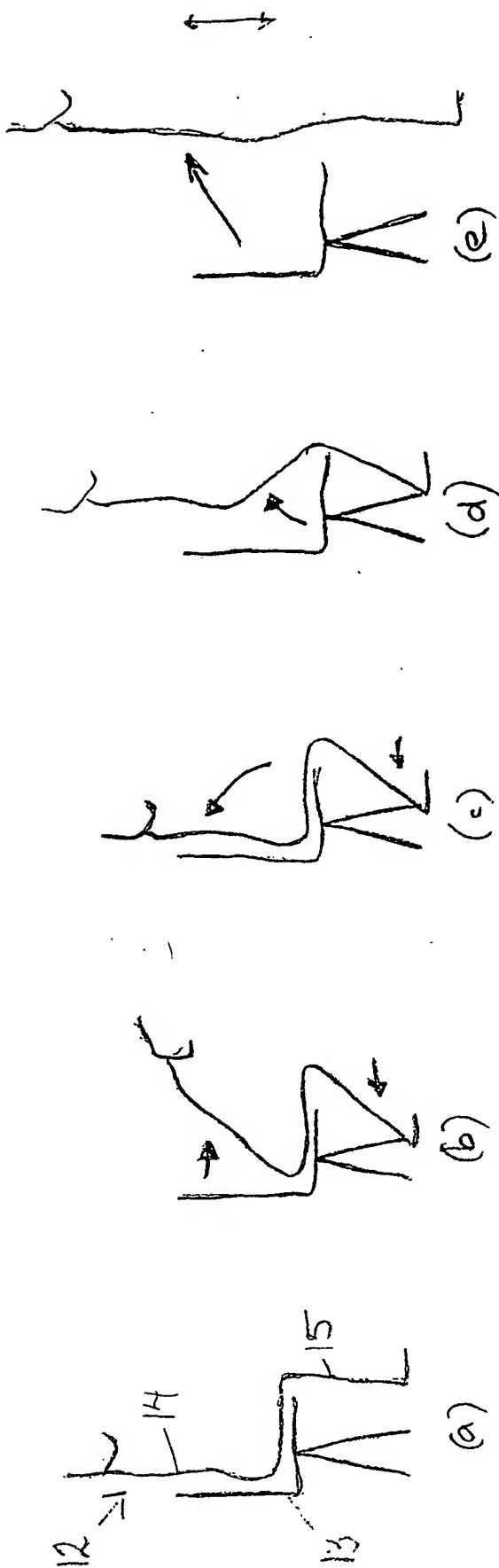
15 32. A method of controlling functional electrical stimulation provided to a portion of a body of a subject, the method comprising the steps of measuring the position and/or movement of a walking aid operated by the subject; and processing the signals and outputting electrical stimulation to said body portion in response to the measured position and/or movement of said walking aid.

20

25 33. A method of controlling functional electrical stimulation provided to a portion of a body of a subject of claim 32 wherein the electrical stimulation is provided to the legs of the subject to cause the subject to walk.

30 34. A method of controlling functional electrical stimulation provided to a portion of a body of a subject of claim 33 further comprising the step of measuring the position and/or movement of the legs and using the measurements to modify or control the electrical stimulation generated in response to movement of the subject's walking aid.

Fig. 1





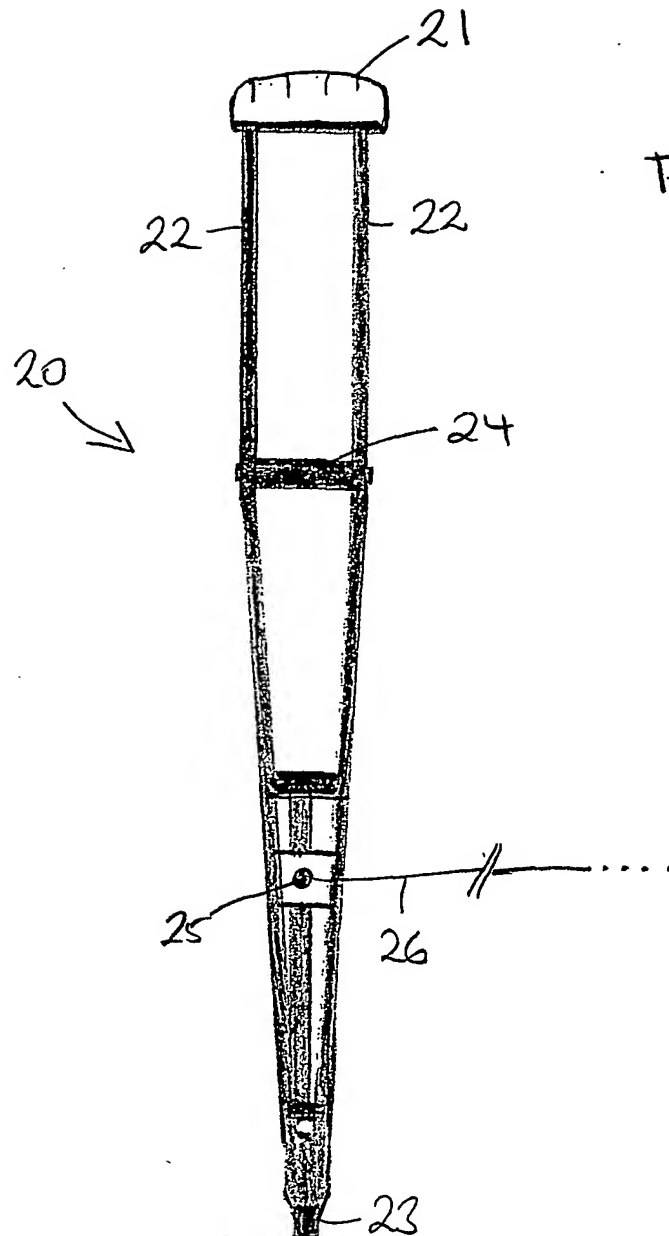
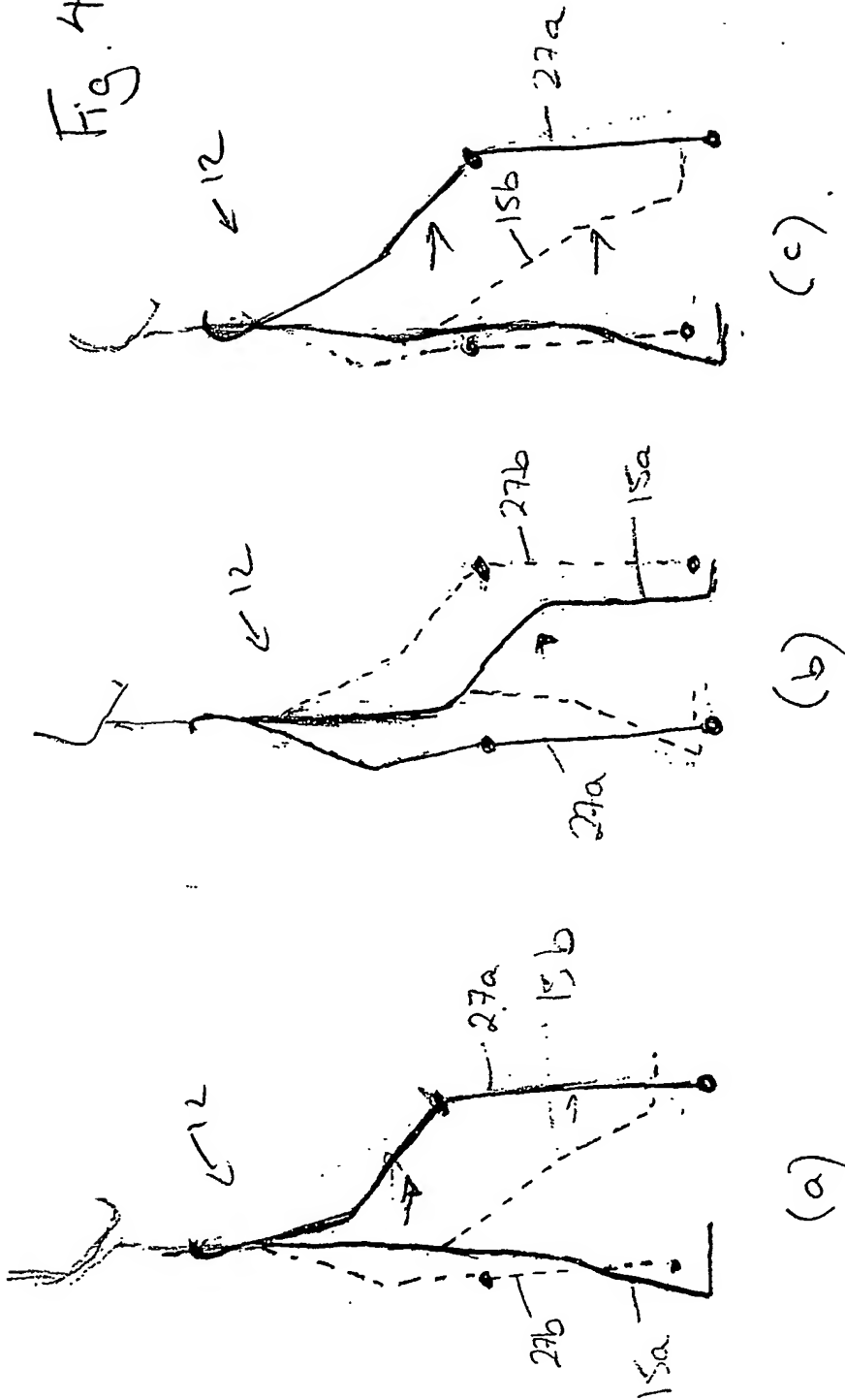
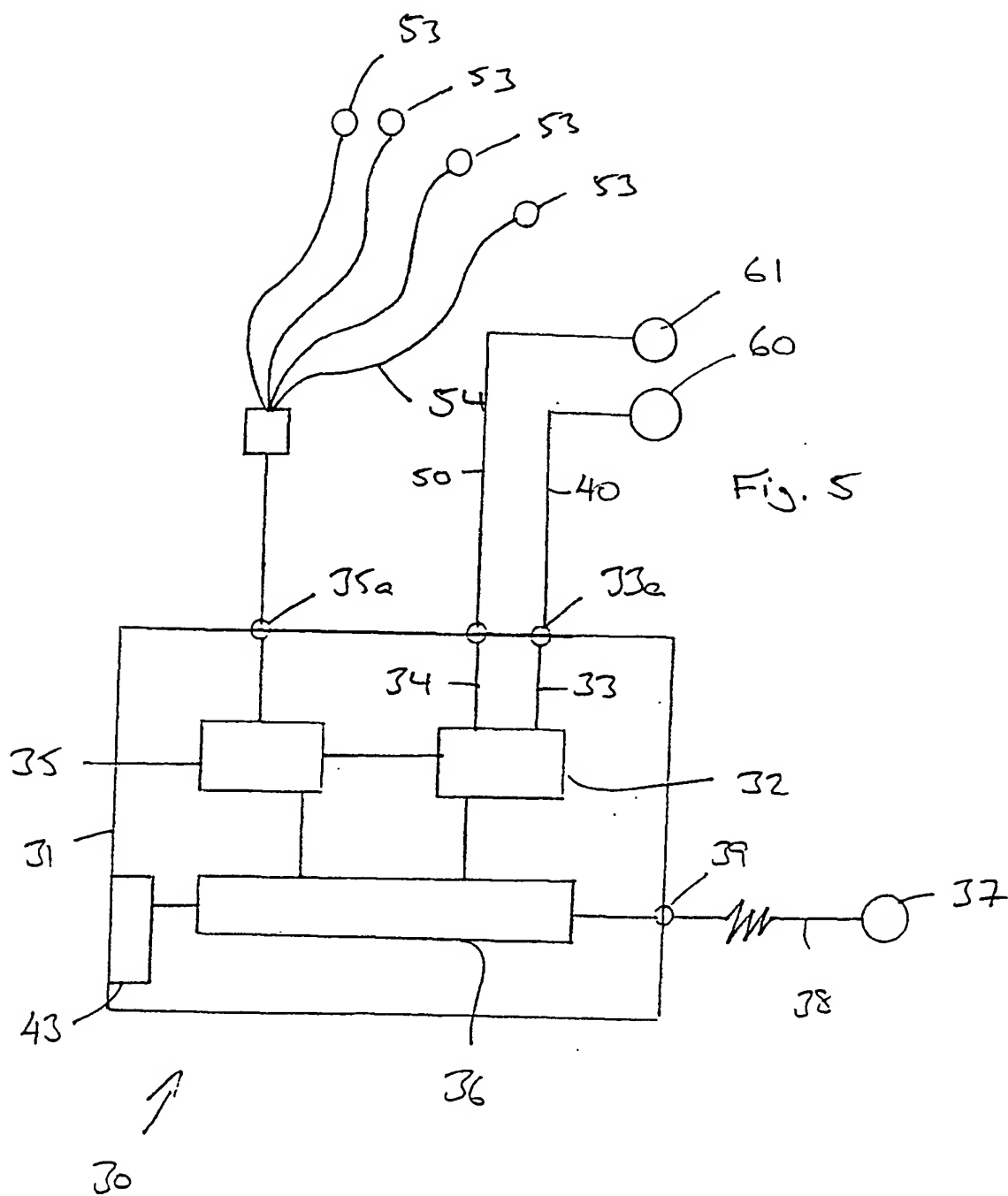



Fig. 4.





## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU01/00992

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>												
Int. Cl. <sup>7</sup> : A61B 5/103, 5/0488, A61N 1/36												
According to International Patent Classification (IPC) or to both national classification and IPC												
<b>B. FIELDS SEARCHED</b>												
Minimum documentation searched (classification system followed by classification symbols)												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI & keywords; body, torso, chest, position, movement, angle, twist, orientation, motion, displacement, rotation, translation, muscle, muscular, arm, hand, limb, thigh, stimulate, electric, electronic, FES												
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>												
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	GB 2302283 A (GEC-MARCONI LIMITED) 15 January 1997 See the abstract	1-17, 28-31										
X	US 4569352 A (PETROFSKY et al) 11 February 1986 See col 1, lines 40 to 62 and figure 2	1-17, 28-31										
X	US 5383911 A (MANN) 24 January 1995 See the abstract	1-17, 28-31										
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex												
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&amp;" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention											
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone											
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art											
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 26 September 2001		Date of mailing of the international search report 5 2 OCT 2001										
Name and mailing address of the ISA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  VINCE BAGSAUSKAS Telephone No : (02) 6283 2110										

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/00992

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/04705 A1 (MOTOROLA INC) 13 February 1997 See page 5, lines 4 to 13; page 6, lines 1 to 10; page 7 line 32 to page 8 line 18; figure 3	1-17, 28-31
X	US 4421336 A (PETROFSKY et al) 20 December 1983 See col 6, lines 47 to 60; col 10, lines 36 to 51; figure 1	18 to 27, 32 to 34
X	US 4724842 A (CHARTERS) 16 February 1988 See figure 1	18 to 27, 32 to 34
A	US 4697808 A (PETROFSKY et al) 6 October 1987	

INTERNATIONAL SEARCH REPORT  
Information on patent family members \*

International application No.  
PCT/AU01/00992

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
GB	2302283	NONE	
US	4569352	NONE	
US	5383911	NONE	
WO	9704705	AU	58704/96
US	4421336	CA	1209679
US	4724842	NONE	
US	4697808	NONE	
END OF ANNEX			